10-year randomized trial (RCT) of zirconia-ceramic and metal-ceramic fixed dental prostheses

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Abstract: OBJECTIVES To monitor zirconia-ceramic and metal-ceramic posterior FDPs with respect to survival and technical/biological complication rates. MATERIALS AND METHODS Fifty-eight patients received 76 3- to 5-unit posterior FDPs. The sites were randomly assigned to 40 zirconia-based (ZC) and 36 metal-based (MC) FDPs. FDPs were examined at baseline (cementation), at 6 months, at 1 year and then yearly up to 10 years. Technical outcomes were assessed using modified United States Public Health Service (USPHS) criteria. Biologic outcomes included probing depth, plaque, bleeding on probing and tooth vitality. Statistical analysis was performed applying Kaplan-Meier (KM) estimation, log-rank, Mann-Whitney and Fisher exact test. RESULTS During the 10-year follow-up thirteen patients (17 FDPs) dropped out and 6 FDPs in 6 patients (5 ZC,1 MC) were considered catastrophic failures for technical and/or biological reasons. Forty-four patients with 53 FDPs (29 ZC, 24 MC) were available for examination. The median observation period was 10.3 years (ZC) and 10.0 years (MC). The 10-year KM survival estimate of ZC FDPs was 91.3% (95%CI:69.5;97.8) and 100% of MC FDPs. Minor chipping of the veneering ceramic and occlusal wear were found to a similar extent at ZC and MC FDPs. ZC FDPs demonstrated a significantly higher rate of framework fracture, de-bonding, major fractures of the veneering ceramic and poor marginal adaption. Biological outcomes were similar in both groups and between abutment and control teeth. CONCLUSION At 10 years, ZC and MC posterior FDPs resulted in similar outcomes for the majority of the outcome measures ($p > 0.05$).

DOI: https://doi.org/10.1016/j.jdent.2018.05.015

10-year randomized trial (RCT) of zirconia-ceramic and metal-ceramic fixed dental prostheses

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Keywords: zirconia, all-ceramics, metal-ceramic, FDP, long-term, technical, biologic

Abstract word count: 245; Total word count: 3595 (incl. abstract); No. of tables/figures 6; No. of references 31

Abstract

Objectives: to monitor zirconia-ceramic and metal-ceramic posterior FDPs with respect to survival and technical/biological complication rates.

Materials and Methods: Fifty-eight patients received 76 3- to 5-unit posterior FDPs. The sites were randomly assigned to 40 zirconia-based (ZC) and 36 metal-based (MC) FDPs. FDPs were examined at baseline (cementation), at 6 months, at 1 year and then yearly up to 10 years. Technical outcomes were assessed using modified United States Public Health Service (USPHS) criteria. Biologic outcomes included probing depth, plaque, bleeding on probing and tooth vitality. Statistical analysis was performed applying Kaplan-Meier (KM) estimation, log-rank, Mann-Whitney and Fisher exact test.

Results: During the 10-year follow-up thirteen patients (17 FDPs) dropped out and 6 FDPs in 6 patients (5 ZC,1 MC) were considered catastrophic failures for technical and/or biological reasons. Forty-four patients with 53 FDPs (29 ZC, 24 MC) were available for examination. The median observation period was 10.3 years (ZC) and 10.0 years (MC). The 10-year KM survival estimate of ZC FDPs was 91.3% (95%CI:69.5;97.8) and 100% of MC FDPs. Minor chipping of the veneering ceramic and occlusal wear were found to a similar extent at ZC and MC FDPs. ZC FDPs demonstrated a significantly higher rate of framework fracture, de-bonding, major fractures of the veneering ceramic and poor marginal adaption. Biological outcomes were similar in both groups and between abutment and control teeth.

Conclusion: At 10 years, ZC and MC posterior FDPs resulted in similar outcomes for the majority of the outcome measures ($p>0.05$).

Introduction

Socio-economic changes, improvements in oral prophylaxis and individually designed oral hygiene regimens followed by a regular maintenance led to a decrease in loss of teeth and a shift to more partially edentulous rather than edentulous patients [1,2]. In these patients there is a need for fixed dental prostheses (FDPs) replacing single or multiple missing teeth. Traditionally, metal-ceramic (MC) FDPs veneered with feldspathic ceramic were considered to be the gold standard [3,4]. Following the demands of clinicians and patients for metal-free reconstructions more recent developments focused on ceramics as framework material. Thereby, the high-strength ceramic zirconia was most promising due to its high flexural strength and fracture toughness [5,6]. The fracture rates of zirconia-based FDPs were low and to occurred at a similar rate as metal-based FDPs [7-11]. Reported shortcomings of zirconia-based FDPs, however, include an increased rate of veneering ceramic fractures and de-bonding of the reconstructions [7,8]. These shortcomings were in part attributed to a lack of precision when using early technologies of CAD/CAM techniques and a lack of anatomical support of the zirconia veneering ceramic. Moreover, the adhesion between zirconia frameworks and the respective veneering ceramics was questioned [12].

Clinical long-term data and randomized controlled studies (RCT) comparing zirconia-based and metal-based FDPs are still scarce. At the present, only a very limited number of non-randomized studies reporting 10-year outcomes of zirconia-ceramic FDPs or of alternative all-ceramic material such as lithium-disilicate and zirconia-reinforced alumina ceramics are available [13-15].

The aim of the present RCT was, therefore, to monitor whether or not the use of posterior FDPs with zirconia frameworks and metal frameworks resulted in similar outcomes with

respect to survival and technical/biological complication rates. The null-hypothesis was that no differences would be found between the two types of FDPs.

Material and Methods

Study design

The present study was designed as a randomized controlled clinical trial and performed according to the requirements of the Declaration of Helsinki. The study is registered in the German Clinical Trials Register (DRKS00006276). Although the study was designed before the introduction of the STROBE guidelines, the demands generally are fulfilled. Prior to the start of the trial, ethical approval was obtained from the local ethical committee and all patients signed an informed consent. The detailed study protocol was described in a previous publication [16].

Patients and reconstructions

Fifty-eight patients (27 female, 31 male) patients in need of at least one FDP in the posterior region of the maxilla or mandible were consecutively recruited and entered the clinical investigation. Patients were only included in the clinical trial if they were in good general health conditions, free from periodontal diseases and had no obvious signs of bruxism. The abutment teeth had to ensure sufficient tooth substance for a proper retention of the FDPs, to be vital or successfully endodontically treated. Seventy-six 3- to 5-unit posterior FDP sites were randomly assigned to FDPs either with zirconia frameworks (zirconia-ceramic FDPs;ZC) or metal frameworks (metal-ceramic FDPs;MC) by means of a computer-generated randomization list and using sealed envelopes. Forty ZC and 36 MC FDPs replacing premolars and molars were inserted (table 1).

Prosthodontic procedures

For both types of FDPs the same treatment procedures were performed according to clinical procedures for metal-ceramic reconstructions. The preparation design of the abutment teeth followed the requirements for computer-aided manufacturing (CAM) [17]. In brief, teeth were prepared with a 1mm circumferential shoulder, a 1.5mm axial and 1.5-2mm occlusal reduction, and a tapering angle between 6° and 10°. All frameworks were manually made out of modeling wax (ZTM Thiel, Erkodent, Pfalzgrafenweiler, Germany) and designed according to the manufacturer's recommendations. Specific care was taken to provide sufficient support for the veneering material. Prior to milling, the design of the ZC frameworks was optically scanned, digitized and enlarged to compensate the estimated sintering shrinkage of about 28% (Cercon brain, DeguDent,Hanau,Germany). The ZC frameworks were fabricated out of white-stage zirconia blanks by means of a CAM-system (Cercon,Degudent,Hanau,Germany) [18]. The MC frameworks were fabricated by means of the lost-wax technique [19]. The wax models were cast out of a gold-alloy (Degudent U,Degudent,Hanau,Germany). The frameworks were veneered with the corresponding veneering ceramics (ZC:Cercon-Ceram-S;MC:Duceram-Plus,Degudent,Hanau,Germany). The interior surface of all FDPs was gently grit-blasted (granule-size 110 μm, pressure 2 bar for 10 seconds) and cleaned with alcohol. Prior to cementation of the FDPs the abutment teeth were pre-treated with a dentin primer (ED Primer,Kuraray). An alloy primer (Alloy Primer, Kuraray, Japan) compatible to the resin cement was used for the pre-treatment interior surfaces of the metal-based FDPs. All FDPs were adhesively cemented using the same resin cement (Panavia 21 TC,Kuraray,Osaka,Japan). If occlusal adjustments were performed after the insertion, the prostheses were thoroughly polished with ceramic polishers (Komet nos. 9425, 9426 and 9457 Brasseler,Savannah,USA).

Baseline and follow-up examinations

Immediately following cementation of the reconstructions, a baseline examination was performed. Patients were recalled at 6 months, at one year and then yearly up to 10 years of follow-up. All clinical examinations (data collection) were performed by the same clinical investigator (IS). At all time-points, the reconstructions were evaluated for survival, and for technical and biological outcomes.

Technical aspects were evaluated using modified USPHS (United States Public Health Service) criteria [20,21] (table 2). In brief, the reconstructions were examined for framework fracture, chipping or fracture of the veneering ceramic, occlusal wear of the veneering ceramic, marginal adaptation and general anatomical shape of the FDPs.

All parameters were rated Alfa in case of no problems, Bravo in case of minor complication, Charlie if the complications were major and Delta if the reconstruction had to be removed due to the complication. Moreover, the rate of de-bonding was assessed.

In the event of complications, patients were informed and attempts were made to preserve the reconstructions. Biological outcome measures at abutment teeth and the respective contra-lateral teeth included: probing depth (PD), probing attachment level (PAL), absence or presence of plaque (plaque control record; PCR) (O'Leary et al. 1972)), bleeding on probing (BOP) and abutment tooth vitality. Tooth vitality was tested both at abutment and contra-lateral control teeth with CO_2. Occlusal and functional relationships between FDPs and opposing jaws were recorded. Finally, peri-apical x-rays of the abutment teeth and clinical photographs of the reconstructions were taken.

Statistical analysis

Descriptive statistics are based on all data, whereas for the statistical test only one FDP per patient was used, which was selected at random in case more than one FDP were available in

a patient. This formed the reduced data set for statistical tests. The random selection was performed by the statistician before analyzing the data somehow.

The reconstructions were rated as *survived* if they were present (with/without complications) at time of follow-up, and as *success* if they were free from any technical (rated Alfa) or biological incidents over the whole observation period in all evaluated parameters.

The analysis of the 10-year survival rate of zirconia-based and metal-based FDPs was performed by use of Kaplan-Meier survival statistical method. The 95% confidence intervals (CI) were added for the discussion of the relevance of the findings.

Patients lost to follow-up were censored. The statistical comparisons on the two survival curves of the FDP groups are using the log-rank test based on the reduced data set.

For the comparisons of PD, PAL, PCR and BOP between test and contralateral control teeth, we calculated the differences of the paired data and applied the Wilcoxon signed rank test for the analyses within a group and the Mann-Whitney test for the analyses between the two groups using the reduced data set.

The Fisher exact test or Pearson chi square test was used for the comparison of the categorical variables based also on the reduced data set.

The level of significance was set at $p<0.05$. Primary endpoint is the survival of the FDPs. All the other endpoints are dealt as secondary ones without corrections for the multiple testing.

Results

The overall examined pool included 58 patients (27 female, 31 male) with 76 FDPs: 3-unit (33 ZC, 34 MC), 4-unit (6 ZC, 1 MC) and 5-unit (1 ZC, 1 MC) FDPs (table 1). Out of these, 44 patients with at least one surviving FDP could be examined at the 10-year recall examination.

Thirteen patients were not available for this examination, either because they had passed away, had moved abroad and could not be contacted any more. Out of these 13 patients, 3 refused a further participation to study because of serious general illness not related to the study. One patient with one FDP had lost the reconstruction before the 10-year follow-up and also did not come to the 10-year examination. The median observation period up to the last examination of the 17 FDPs in the 13 patients, who did not show up for the 10-year recall-examination, amounted to 5.3 years for ZC (95%CI:4.5;5.5) and to 4.5 year for MC (95%CI:2.9;4.8).

Up to the 10-year follow-up, 6 FDPs in 6 patients were considered catastrophic failures for technical and/or biological reasons. Hence, these FDPs were lost during the follow-up at some point and were not available for the 10-year examination. In 5 of these 6 patients additional study FDPs could be examined.

The reasons for the loss of the FDPs were (for details see table 3):

- Group ZC:

  2 FDPs lost due to framework fractures

  3 FDPs lost due to loss of one of the abutment teeth (fracture, endodontic failure)
- Group MC:

  1 FDP lost after de-bonding and inability to re-cement

The remaining 53 FDPs (29 ZC, 24 MC) in 44 patients were evaluated at a median observation time of 10.3 years for ZC (range 9.5–11.1y) and 10.0 years for MC (range 8.6–

11.5y). Twenty-two patients had ZC FDPs and the same number of patients had MC FDPs. The mean age of these patients at this follow-up was 60.9 (range 36.5-86.9 years).

Technical outcomes

The technical outcomes of the ZC and MC FDPs overall exhibited no significant differences for any of the parameters at the 10-year follow-up ($p>0.05$) (4). Chipping of the veneering ceramic was similar at the ZC and MC FDPs.

Differences occurred, however, when the number of clinically acceptable technical problems (rated Bravo) and clinically inacceptable technical complications (rated Charlie or Delta) were compared between the ZC and MC FDPs (table 4, figure 1). As an example, *minor chipping of the veneering ceramic* (rated Bravo) happened to a similar extent at ZC and MC FDPs (ZC 37.9% vs. MC 33.3%). Yet, *major fractures of the veneering ceramic* (rated Charlie) were only observed at ZC FDPs (ZC 13.8%, MC 0%). Furthermore, *clinically inacceptable marginal adaption of the reconstruction* (rated Delta) only occurred at ZC FDPs (ZC 10.3% vs. MC 0%).

F*ractures of frameworks* happened at 2 ZC FDPs, whereas none of the MC FDPs exhibited a framework fracture (fracture rate ZC 5.9%, MC 0%) up to the 10-year follow-up.

Finally, *de-bonding* was detected at 6 FDPs during the observation period (5 ZC, 1 MC). At ZC FDPs, all de-bonding were adhesive failures of the cement to the dentin with the entire cement attaching to the zirconia surface. The failed MC FDP could, unfortunately, not be analysed in detail, because the patients had misplaced the de-bonded reconstruction and was not able to find it anymore.

Two of the de-bonded ZC reconstructions were successfully removed and re-cemented using the same resin cement and pre-treatment as initially used (Panavia 21). Two further de-bonded FDPs (1 ZC, 1 MC) could not be re-cemented and were recorded as loss (table 3). The

two remaining de-bonding were detected at the 10-year follow-up examination (2 ZC). These 2 ZC FDPs were rated as *surviving* in the present data since they were still present at time of the 10-year examination but had to be replaced after the 10-year examination.

Table 1 shows the minor differences of the distribution of the number of units in a FPD in the full data set and the reduced one. Based on the reduced data set of one randomly selected FDP per patient for statistical comparison of the groups and in consideration of the patients lost to follow up, the Kaplan Meier 10-year survival estimate of ZC FDPs was 91.3% (95%CI:69.5;97.8). The corresponding 10-year survival estimate of the MC FDPs was 100%. The difference was not statistically significant (p=0.1484).

The 10-year technical complication rate as calculated with Kaplan Meier method demonstrated statistically significant difference between the two groups for the rate of framework fractures (MC=0%/ZC=4.6% (95%CI:0.7;28.1)); major fractures of veneering ceramic (Charlie/Delta): MC=0%/ZC=18.9% (95%CI:7.1;45); inacceptable marginal adaptation ((Charlie/Delta): MC=20.8% (95%CI:8.9;44.3)/ZC=50.3% (95%CI: 25.8;80.5)) and de-bonding (MC=0%/ZC=22.7% (95%CI:8.3;53.5)) (see figure 1a).

Further technical outcome measures such as minor fracture of veneering ceramic (Bravo) (MC=42.6% (95%CI:25.5; 64.9)/ZC=54.8% (95%CI:75.7;36)); minor occlusal wear (Bravo) (MC=95.1% (95%CI:80.3;99.7)/ZC=96.2% (95%CI:83.6;99.7)); major occlusal wear (Charlie/Delta) (MC=63.5% (95%CI:22.1;98.3)/ZC=34.7% (95%CI:18.9;57.8)) and acceptable marginal adaption (Bravo) (MC=84.2% (95%CI:56.2;98.4)/ ZC=74.0% (95% CI:56.2;89.0)) did not reveal significant differences between the groups (see figure 1b).

When the data were analyzed with respect to the *time until a technical complication occurred (time to event)* with the logrank test, it was observed that minor occlusal wear of the veneering ceramic (USPHS rated Bravo) occurred earlier at the ZC than at MC FDPs

(p=0.0189), yet at 10 years the wear was found to a similar extent at the ZC and MC FDPs. The time to event analysis demonstrated no statistically significant differences between the two groups for most of the other evaluated parameters like: marginal adaptation p=0.6286 (for Bravo) and p=0.2955 (for Charlie/Delta); framework fracture p=0.3066; fracture of veneering ceramic p=0.2513 (for Bravo); occlusal wear p=0.4968 (for Charlie/Delta).

Finally, no association between the incidence of occlusal wear/roughness and the incidence of chipping of the veneering ceramic was found for ZC (p=0.6364, Pearson Chi Square test) and MC (p=1.000).

Biological outcomes

Secondary caries occurred at 1 MC and at 4 ZC FDPs during the 10 years of observation. At four (3 ZC, 1 MC) out of these 5 FDPs exhibiting secondary caries at the abutment teeth, the marginal adaptation was rated Charlie or Delta before. The correlation of the two complications did not reach statistical significance.

All other biologic outcomes measures were similar for ZC and the MC FDPs with no statistically significant differences for PD, PAL, PCR, BOP and vitality of abutment and untreated contralateral control teeth as well as for radiographic outcomes of abutment teeth (see 5).

Finally, the biological outcomes at abutment teeth (test) as compared to control teeth were similar in both groups (ZC, MC).

At 10-years only one ZC FDP (2.5%) and no MC FDP (0%) were free of complications (i.e. successful).

Discussion

In the present RCT, posterior ZC and MC FDPs exhibited excellent 10-year survival rates with no statistical differences between groups. Fracture of a FDP framework was a very rare complication, only occurring at 2 ZC FDPs during the 10-year of follow-up.

Furthermore, the overall technical outcome was similar for both types of FDPs ($p>0.05$). Yet, when analysing in more detail, discriminating clinically acceptable from inacceptable complications, differences were observed. Minor superficial chipping (USPHS rate Bravo) of the veneering ceramic occurred similarly at ZC and MC, yet, clinically inacceptable major fractures of the veneering ceramic (USPHS rate Chalie/Delta) were only observed for ZC FDPs. De-bonding occurred more frequently at the ZC FDPs and the marginal adaption was judged clinically inacceptable more often at ZC FDPs than at MC FDPs.

From a biologic point of view, both types of FDPs exhibited favorable results with no differences between the groups for the majority of the assessed periodontal parameters ($p>0.05$). A slightly higher rate for secondary caries in the marginal areas of the FDPs was found at the ZC abutment teeth than at the MC abutment teeth, though.

Zirconia-ceramic tooth-supported FDPs were investigated in numerous clinical studies in the past decade, recently allowing for meta-analyses of their outcomes [7,8]. Most of the studies on zirconia FDPs evaluated posterior bridges replacing one to three missing teeth, analogous to the present investigation. The short to medium term observation period showed favourable outcomes of zirconia-ceramic FDPs with very low or no fracture rates of the frameworks [7,8,10,11,22-24].

Long-term studies reporting on all-ceramic FDPs are still scarce today. The few studies reporting on long-term outcomes of all-ceramic FDPs analysed 3-unit FDPs made out of

glass-infiltrated alumina ceramics and reinforced glass-ceramics [14,15]. These studies reported on promising outcomes of the all-ceramic FDPs. One study using glass-infiltrated zirconia reinforced alumina ceramic reported a 10 year survival rate of 93.6%, the other study testing monolithic lithium-disilicate ceramic FDPs reported a 10 year survival rate of 87.9% [14,15]. In both studies, fractures of the 3-unit all-ceramic FDPs were the predominant reason for failure. The 10-year survival rates of the zirconia-ceramic FDPs in the present RCT were lower than the one of glass-infiltrated zirconia reinforced alumina ceramic reconstructions, but higher than the one of lithium-disilicate reconstructions. Furthermore, in the present RCT fractures of a 3- and of a 5-unit zirconia-ceramic FDP were observed during the 10-year follow-up. Thus, catastrophic fractures leading to a loss of the reconstruction can be found for all types of ceramic frameworks at different rates, and depending on the type of ceramic.

Until today, only one study is reporting on 10-year outcomes of zirconia-ceramic FDPs [13]. The survival rate of the zirconia FDPs in that study was quite low with 67% at 10 years [13]. This study evaluated FDPs with zirconia frameworks made with a prototype CAM procedure (Direct Ceramic Machining, DCM, [18]) and at time of the study, clinical guidelines for the preparation of the abutment teeth for CAD/CAM reconstructions and the handling of the zirconia frameworks were lacking. Several clinical problems related to this were observed in that study [13] at 10 years, like and secondary caries at marginal gaps. The results might not be fully representative for the procedures available today. The soft- and hardware of the CAD/CAM technology has significantly evolved in the last decade, and the accuracy of the procedures has been improved [25]. Internal gap values of zirconia FDP frameworks in the literature ranged from 140(±26)µm in laboratory studies and 130(±56)µm in clinical studies [26,27]. Yet, more recently, values for the internal gaps of zirconia frameworks of 88.27(±41.49)µm and 92.13 (±49.87)µm were reported [28]. The introductions of clinical

guidelines for the preparation of the abutment teeth for CAD/CAM reconstructions led to further improvement [17,29].

The CAM procedure tested in the present study (Cercon, Degudent) was a further development of the previously mentioned DCM system, yet, the software applied for the fabrication of the presently tested zirconia frameworks was the first variation for this system. The results of the present study indicate that some improvements were still needed. A clinical study of the internal gaps of the present zirconia and metal FDP frameworks displayed that the zirconia frameworks exhibited significantly larger internal gaps than the metal frameworks in cervical, axial and occlusal regions [30]. The cervical regions differed with 189.6(±71.8)µm for zirconia frameworks vs. 118.6(±31.5)µm for metal frameworks. In axial regions the difference was 140.5(±38.3)µm for zirconia frameworks vs. 95.7(±18.1)µm for metal frameworks [30]. Interestingly, the present 10-year study displayed more de-bonding incidences at the zirconia FDPs than at metal-ceramic FDPs, although cemented identically. Furthermore, secondary caries was more often found in the marginal regions of the zirconia-ceramic FDPs than at the metal-ceramic FDPs.

Chipping of the veneering ceramic was one of the primary complications at zirconia-ceramic FDPs in the literature. Worrying chipping rates of up to 25% were reported in early prospective studies of zirconia-ceramic FDPs [10], inducing a general doubt for zirconia-ceramics. In addition, a systematic review on zirconia-ceramic and metal-ceramic FDPs documented significantly higher rates for chipping at the zirconia-ceramic FDPs (54% ZC vs. 34% MC) [7]. Due to this, different classifications for the rating of chipping were discussed [31]. In the present study a modified USPHS classification was used [21], discriminating between clinically acceptable minor chipping (rated Bravo) and inacceptable major chip off fractures of the veneering ceramic rated Charlie/ Delta).

Surprisingly, the incidence of the minor chippings (Bravo) was similar for zirconia- and metal-ceramic FDPs (38% ZC vs. 33% MC) at 10 years. However, major fracture of the veneering ceramic (Charlie/Delta) only occurred at zirconia-ceramic FDPs. The chippings were correlated with occlusal wear of the veneering ceramic in both groups, as a fractographic analysis of the replicas of the FDPs with chipping showed [32].

Chipping of the veneering ceramic is a problem at metal-ceramic FDPs [33], as well as at zirconia-ceramic FDPs [9], yet, the extension of the zirconia veneering ceramic chipping was larger. This issue has been analysed before and despite further development of the materials and the techniques it appears not to be fully resolved [7]. Moreover, the only comparable long-term study with a 10-year observation period of veneered all-ceramic FDPs reported also a relatively high cumulative total chipping rate of 37.7%. The authors assumed that the CAD software used in that early stage was not capable to create an adequate anatomical support of the framework for the veneering ceramic [14]. Future concepts may need to focus on monolithic zirconia FDPs to reduce this specific complication rate, yet, this assumption needs to be tested in laboratory and clinical research.

The biologic integration of the zirconia- ceramic and the metal-ceramic FDPs was similar at 10 years. No differences in the periodontal parameters (PD, PAL and BOP) were found, and loss of vitality occurred similarly in both groups. These findings are in accordance to the published results on zirconia-ceramic FDPs [8,34].

In conclusion, the present study demonstrated similar survival rates of zirconia-ceramic FDPs and metal-ceramic FDPs at 10 years. Clinical recommendations, however, need to be made with caution due to the limited sample size in the present RCT. Furthermore, higher technical complication rates of the zirconia veneering ceramic have to be considered. Finally, this RCT was underpowered to observe truly significant differences. Future studies should take into

account, that a sample size of approximately 260 patients in total with a power of 80% is needed to detect a difference of the survival rates of 10%.

Funding:

This study was funded by an industrial grant (DeguDent GmbH, Dentspy Sirona, Germany)

Illustrations and Tables

	3 units	4 units	5 units	
ZC FDPs	33	6	1	40
reduced	20	6	1	27
MC FDPs	34	1	1	36
reduced	29	1	1	31
Total	67	7	2	76
reduced	49	7	2	58

Table 1: Overview of the examined FDPs including the number of FDP units per group in the full data set and in the reduced data set

USPHS	Alfa	Bravo	Charlie	Delta
Framework fracture	No fracture of framework			Fracture of framework
Veneering fracture	No fracture	Chipping, but polishing is possible	Chipping down to the framework	New reconstruction is needed
Occlusal wear	No occlusal wear on reconstruction or on opposite teeth	Occlusal wear on reconstruction or on opposite teeth is < 2mm	Occlusal wear on reconstruction or on opposite teeth is > 2mm	New reconstruction is needed
Marginal adaptation	No probe catch	Slight probe catch, but no gap	Gap with some dentine or cement exposure	New reconstruction is needed
Anatomical form	Ideal anatomical shape; good proximal contact	Slightly over or under contoured, weak proximal contact	Highly over or under contoured, open proximal contact	New reconstruction is needed
Tooth vitality	Significantly positive (CO_2); negative at existing root canal filling	Uncertain or delayed positive; no sensitivity on percussion, no whitening	Clearly negative, no root canal filling present or periapical lesion treatment needed	Abutment tooth to be extracted, removal of FDP needed

Table 2: The modified USPHS criteria

ZC	**f**	**35-x-37**	**1991**	**Longitudinal fracture of abutment tooth (35)**
ZC	**f**	**35-x-37**	**2232**	**Caries profunda, debonding and subsequent extraction of abutment tooth (35)**
MC	**f**	**47-x-45**	**2519**	**De-bonding at both abutment teeth**
ZC	**m**	**17-x-x-x-13**	**2835**	**Framework fracture**
ZC	**f**	**36-x-38**	**2938**	**Framework fracture**
ZC	**m**	**25-x-27**	**2992**	**Endodontic failure and root fracture (25)**

Table 3: Details on the 6 FDPs lost during the observation period, with patient gender, FDP sites, and time and reasons for loss of FDPs

	USPHS				Type of FDP	p value ZC vs MC
	Alfa	**Bravo**	**Charlie**	**Delta**		
Veneering ceramic chipping/ fracture	48.3%	37.9%	13.8%	0.0%	**ZC**	p=0.0701
	66.7%	33.3%	0.0%	0.0%	**MC**	
Occlusal wear	3.6%	64.3%	28.6%	3.6%	**ZC**	p=0.9254
	4.2%	70.8%	25%	0.0%	**MC**	
Marginal adaptation	13.8%	51.7%	24.14%	10.3%	**ZC**	p=0.6655
	20.8%	58.33%	20.83%	0%	**MC**	
Anatomical form	92.9%	7.1%	0.0%	0.0%	**ZC**	p=0.2104
	100%	0.0%	0.0%	0.0%	**MC**	
Tooth vitality	78.6%	17.9%	3.6%	0.0%	**ZC**	p=0.7041
	75.0%	20.8%	4.2%	0.0%	**MC**	

Table 4: Descriptive technical outcomes of all examined bridges at the 10-year follow-up, given with USPHS-ratings of the zirconia-ceramic (ZC) and metal-ceramic (MC) FDPs in % and statistical comparison of the technical outcomes between ZC and MC FDPs (reduced data set with Fisher exact test).

		Biologic parameters			
		PD (mm)	PAL (mm)	PCR (%)	BOP (%)
ZC	Mean±STD	2.5±0.3	-0.1±0.4	14±16	26±29
	Median	2.6	-0.1	13	19
MC	Mean±STD	2.6±0.5	0.0 ± 0.3	10±17	26±27
	Median	2.8	0.0	0	13
p value		0.15	0.15	0.17	0.74

Table 5: Ten- year biologic outcomes - mean values of PD (probing depth), PAL (probing attachment level), PCR (plaque control record), BOP (bleeding on probing). P-values of the Mann-Whitney test.

Figure legend Fig.1a, b:

Comparison of the significantly different and the non-different technical outcomes of the zirconia-ceramic and metal-ceramic FDPs as rated by USPHS criteria at 10 years.

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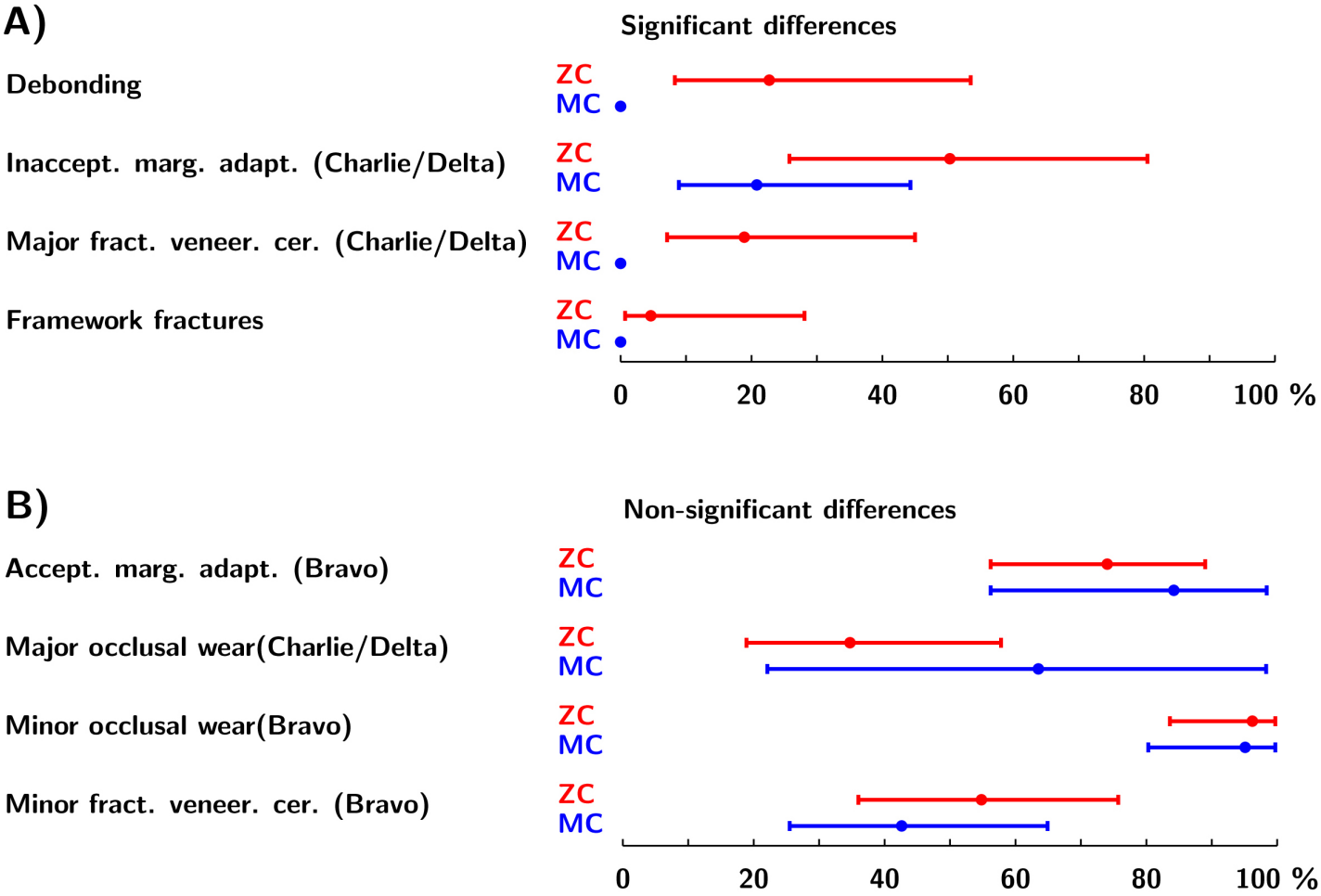
A)
Significant differences
Debonding
Inaccept. marg. adapt. (Charlie/Delta)
Major fract. veneer. cer. (Charlie/Delta)
Framework fractures
ZC
MC
0
20
40
60
80
100 %
B)
Non-significant differences
Accept. marg. adapt. (Bravo)
Major occlusal wear(Charlie/Delta)
Minor occlusal wear(Bravo)
Minor fract. veneer. cer. (Bravo)
ZC
MC
0
20
40
60
80
100 %

Figure 1